



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/852,966 | 05/10/2001 | Rima Kaddurah-Daouk | AVZ-020CN | 5588 |

959 7590 07/02/2008
LAHIVE & COCKFIELD, LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

| |
|----------|
| EXAMINER |
|----------|

HARTLEY, MICHAEL G

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1618

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

07/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte RIMA KADDURAH-DAOUK

Appeal 2008-0229
Application 09/852,966
Technology Center 1600

Decided: June 30, 2008

Before DEMETRA J. MILLS, ERIC GRIMES, and RICHARD M.
LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for modulating energy flow or reserves in the skin. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). Because we conclude that two of the references cited by the Examiner anticipate the pending claims, we vacate the appealed rejection and enter new grounds of rejection.

BACKGROUND

“The creatine kinase/creatine phosphate energy system is only one component of an elaborate energy-generating system found in tissue with high and fluctuating energy requirements. The components of the creatine energy system include the enzyme creatine kinase, the substrates creatine and creatine phosphate, and the transporter of creatine. ... Some of the functions associated with this system include efficient regeneration of energy in cells . . . and involvement in signal transduction-pathways” (Spec. 1). “[C]reatine is an excellent stimulant of oxidative phosphorylation and high energy production. Creatine has been extensively used by body builders as a means of stimulating energy production in the skeletal muscle” (*id.*).

The Specification discloses “methods for protecting skin tissue against age-related damage or insults such as harmful UV radiation, stress and fatigue by preserving energy pools and protecting against free radical production and oxidative stress ... by administering an amount of a creatine compound” (*id.* at 2).

DISCUSSION

1. CLAIMS

Claims 68-70, 72, 73, 75-85, and 88 are pending and on appeal.

Claims 68-70 are representative and read as follows:

Claim 68: A method for increasing energy reserves in the skin of a subject, comprising
administering to said subject an effective amount of creatine or a salt thereof, such that the energy reserves in the skin of said subject is increased, wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue.

Claim 69: A method for sustaining energy production in the skin of a subject, comprising
administering to said subject an effective amount of creatine or a salt thereof, such that energy production the skin of said subject is sustained,
wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue.

Claim 70: A method for modulating energy flow in the skin of a subject, comprising
administering to said subject an effective amount of creatine or a salt thereof, such that the energy flow in the skin of said subject is modulated,
wherein said subject is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue.

2. APPEALED REJECTIONS

Claims 68-70, 75-80, 84 and 85 stand rejected under 35 U.S.C. § 103 as obvious in view of Yu,¹ Kaddurah-Daouk '731,² and Kaddurah-Daouk '063.³ Claims 68-70, 75-85, and 88 stand rejected under 35 U.S.C. § 103 as obvious in view of Le Fur,⁴ Carniglia,⁵ and Kaddurah-Daouk '063 or Kaddurah-Daouk '030.⁶

The Examiner relies on Yu as disclosing “a treatment of abnormal skin-conditions[](skin aging, wrinkles, psoriasis, etc) associated with aging” using a composition comprising creatine, among other things (Ans. 4), but not the use of creatine to modulate energy flow in the skin (*id.* at 5).

¹ Yu et al., US 5,702,688, Dec. 30, 1997.

² Kaddurah-Daouk et al., US 5,324,731, June 28, 1994.

³ Kaddurah-Daouk et al., WO 96/14063, May 17, 1996.

⁴ Le Fur et al., US 5,256,649, Oct. 26, 1993.

⁵ Carniglia, US 4,871,718, Oct. 3, 1989.

⁶ Kaddurah-Daouk et al., US 5,321,030, June 14, 1994.

Similarly, the Examiner relies on Le Fur and Carniglia in combination to suggest a cosmetic composition comprising creatine (*id.* at 7-8).

The Examiner relies on the Kaddurah-Daouk patents as suggesting use of creatine to modulate energy flow and energy levels (*id.* at 5-6 and 8) and concludes that the claimed method would have been prima facie obvious (*id.* at 6-7, 8).

Our review of the references and arguments leads us to conclude that the Examiner did not rely on the most pertinent facts when considering the prior art. In our view, both Yu and Kaddurah-Daouk '063 anticipate the appealed independent claims 68-70. We therefore vacate the Examiner's rejection and enter the new grounds of rejection set forth below.

3. ANTICIPATION BY YU

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 68-70 are rejected under 35 U.S.C. § 102(b) as anticipated by Yu.

Yu discloses "treatment to alleviate cosmetic conditions and symptoms of dermatologic disorders," including age spots, wrinkles and skin changes associated with aging, with amphoteric compositions containing alpha hydroxyacids (Yu, abstract). Yu also discloses that the amphoteric and pseudoamphoteric compounds that may be incorporated into the compositions include creatine (*id.* at col. 34, ll. 3-7). Thus, Yu discloses the instantly claimed method steps of administering creatine to a subject suffering from a skin disorder associated with aging. Therefore, the methods disclosed by Yu appear to meet all of the limitations of claims 68-70.

In response to the Examiner's rejection, Appellant argued that, while Yu discloses methods of treating skin disorders with a composition "comprising an amphoteric compound and at least one of an alpha hydroxyacid or an alpha ketoacid" as the active agent, the "amphoteric compounds are merely included in the amphoteric composition to modulate the pH of the composition and to control the release of the 'active ingredients'" (App. Br. 5-6). Thus, Appellant argues that Yu "fails to teach or suggest that an amphoteric compound (e.g., creatine) would be useful in any other capacity other than to balance the pH and enhance the ability of the alpha ketoacids and the alpha hydroxyacids to penetrate the skin" (*id.*).

We are not persuaded by this argument. As set forth above, Yu discloses a method having all of the instantly claimed method steps of claims 68-70 (i.e., administering creatine to a subject having a skin disorder associated with aging). Although Yu does not disclose that the administered creatine affects "energy" in a subject suffering from one of the specifically identified skin disorders recited in the claims, Yu treats the same subjects with the same agent as recited in claims 68-70. Therefore, the treatment method taught by Yu would inherently cause the same results as the claimed method.

"[W]hen considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005). Thus, the fact that Yu did not recognize

the benefit provided by creatine is immaterial to the question of whether the disclosed method anticipates the instant claims.

4. ANTICIPATION BY KADDURAH-DAOUK '063

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 68-70 are rejected under 35 U.S.C. § 102(b) as anticipated by Kaddurah-Daouk '063.

Kaddurah-Daouk '063 discloses “methods of treating diseases of the nervous systems ... by administering ... a compound or compounds which modulate one or more of the structural or functional components of the creatine kinase/phosphocreatine system,” such as creatine, creatine phosphate, or analogs of creatine or creatine phosphate (Kaddurah-Daouk '063, pg. 4, ll. 2-8). Kaddurah-Daouk '063 also discloses that “diseases susceptible to treatment with creatine compounds according to the present invention include ... aging” (*id.* at pg. 4, l. 22 to pg. 5, l. 4). Thus, Kaddurah-Daouk '063 discloses the instantly claimed method steps of administering creatine to an aging person; i.e., a subject suffering from a skin disorder associated with aging. Therefore, the method disclosed by Kaddurah-Daouk '063 meets all of the limitations of claims 68-70.

Appellant argues that Kaddurah-Daouk '063 does not disclose “methods for increasing energy reserves, sustaining energy production and modulating energy flow in the skin by administering ... creatine or a salt thereof to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue” (App. Br. 9).

We are not persuaded by this argument. Claims 68-70 only require the administration of creatine (or a salt thereof) to a subject suffering from a

skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue in an amount sufficient to increase energy reserves, sustain energy production, or modulate energy flow, respectively, in the skin of the subject. The Specification states that doses of creatine as low as 0.0001 mg per kilogram of body weight may be effective (Spec. 16: 34-36). Kaddurah-Daouk '063 states that the "actual amount of drug administered will depend on factors such as the size and age of the individual" (Kaddurah-Daouk '063, p. 31, ll. 11-12), and that creatine phosphate has been administered intravenously at doses of up to 8 g/day (*id.* at p. 31, ll. 16-18). Therefore, Kaddurah-Daouk '063 reasonably appears to disclose dosages that are within the range taught by the instant Specification to be sufficient to increase energy reserves, etc.

Given that Kaddurah-Daouk '063 discloses the administration of an energy modulating amount of creatine (or a salt thereof) to a subject suffering from aging (and therefore also suffering from skin disorders associated with aging), Kaddurah-Daouk '063 discloses a method having all of the instantly claimed method steps of claims 68-70. According to *Perricone, supra*, the fact that Kaddurah-Daouk '063 does not disclose or suggest that the administered creatine would modulate energy in the skin as required by claims 68-70 is not dispositive since skin energy modulation is an inherent result administering creatine in the method disclosed by Kaddurah-Daouk '063.

SUMMARY

We vacate the Examiner's obviousness rejection of claims 68-70, 72, 73, 75-85, and 88, and enter a new ground of rejection of claims 68-70 based

on anticipation. We have not entered new rejections of the dependent claims but in the event of further prosecution (see below), the Examiner should consider whether any of the dependent claims should also be rejected over the prior art.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 CFR § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner

(2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record

VACATED, 37 CFR § 41.50(b)

Ssc

Appeal 2008-0229
Application 09/852,966

LAHIVE & COCKFIELD, LLP
ONE POST OFFICE SQUARE
BOSTON, MA 02109